

**REMARKS**

Reconsideration and withdrawal of the claim rejections are requested in view of the amendments and remarks herein.

**I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 26, 28-33 and 36-42 are under consideration in this application. Claims 26 and 31 have been amended; claim 42 has been added to round out the scope of protection to which Applicants are entitled. Support is found throughout the specification. Specifically, support for claim 42 can be found on page 18, line 18, of the application. No new matter is added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

**II. THE REJECTIONS UNDER 35 U.S.C. §112, 1<sup>ST</sup> PARAGRAPH ARE OVERCOME**

Claims 26, 28-33 and 37-41 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. The rejection is traversed.

The Office Action alleges that only the nucleic acid molecule of SEQ ID NO:1, encoding the entire  $\alpha$ -glucosidase from potato of SEQ ID NO:2. The recitation of “derivatives or parts” of those sequences has been removed from claim 26. Claim 26 also recites nucleic acid molecules that have over 70% homology to SEQ ID NO:1. This recitation clearly meets the written description requirements of §112, first paragraph.

*Enzo Biochem Inc. v. Gen-Probe Inc.* (Fed. Cir. 01-1230; July 2002) holds that a functional description of genetic material may be sufficient to satisfy the written description requirement of 35 U.S.C. §112, since the requirement can be met by showing that invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, including functional characteristics, when coupled with known or disclosed correlation between function and structure.

Applicants have clearly provided relevant, identifying structural characteristics in the form of the nucleotide sequence of potato  $\alpha$ -glucosidase. Further, they have provided examples in the application demonstrating the functional properties of the nucleic acid molecule and a correlation between function and structure. There are reasonable limits regarding what the claimed nucleic acid molecules can comprise. The fact that they are not necessarily required to comprise the exact disclosed sequence does not render them inadequately described.

Furthermore, limiting the Applicants to only the nucleotide sequence of SEQ ID NO:1 would unfairly narrow the scope of the invention. For example, other parties could use nucleic acid molecules distinct from SEQ ID NO:1 that encode a structurally and/or functionally identical enzyme to practice this very invention, and they would fall outside the literal scope of the claims. Such a consequence is obviously contrary to the intended function of the patenting system.

Claims 26, 28-33 and 37-41 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

The Office Action alleges that undue experimentation would be required to arrive at the multitude of non-exemplified nucleic acid molecules encoding proteins with the function of a potato  $\alpha$ -glucosidase. As stated in the first line of MPEP §2164.02, “[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed.” *In re Goffe*, 191 U.S.P.Q. 429, 431 (“To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for ‘preferred’ materials in a process . . . would not serve the constitutional purpose of promoting progress in the useful arts.”). Moreover, the specification contains an entire section, beginning on page 44, regarding how to characterize starch in order to determine whether it has been modified by the activity of  $\alpha$ -glucosidase. It is submitted that claim 26 recites both structure and function, and that undue experimentation would not be required by one skilled in the art to reach a nucleic acid molecule covered by claim 26 or its dependent claims.

Consequently, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph, are in order and such relief is requested.

### **III. THE REJECTION UNDER 35 U.S.C. §102 IS OVERCOME**

Claims 26, 28-33 and 37-41 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Nickerson *et al.* The rejection is traversed.

The  $\alpha$ -glucosidase disclosed and claimed in the present application is significantly different from that of Nickerson *et al.* Sequence similarity analysis between the  $\alpha$ -glucosidase proteins of Nickerson *et al.* and of SEQ ID NO:2 reveals only 20.9% identity (see Annex 1), which is clearly outside of the scope of the claims. Thus, Nickerson *et al.* do not disclose or anticipate the instant invention.

Reconsideration and withdrawal of the §102 rejection are requested.

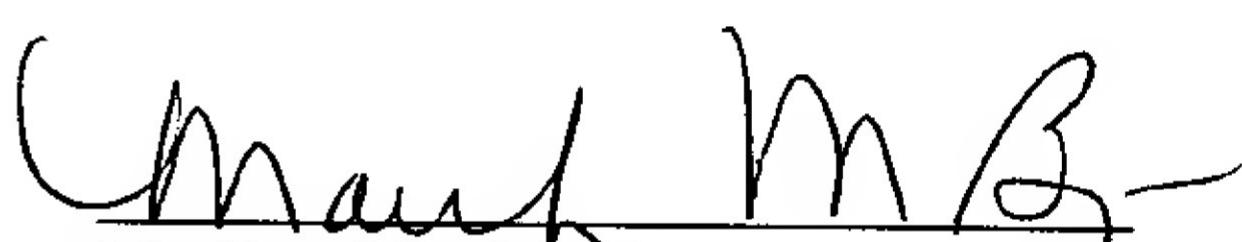
**CONCLUSION**

In view of the remarks and amendments herewith, it is believed that the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the claims:**

26. (Amended) A nucleic acid molecule encoding a protein with the function of a potato  $\alpha$ -glucosidase, selected from the group consisting of
- a) nucleic acid molecules which encode a protein which encompasses the amino acid sequence stated under SEQ ID NO: 2 [or its derivatives or parts],
  - b) nucleic acid molecules which encompass the nucleotide sequence shown under SEQ ID NO: 1 [or its derivatives or parts, or a corresponding ribonucleotide sequence];
  - c) nucleic acid molecules which [specifically hybridize with, or are complementary to, the nucleic acid molecules stated under a) or b), and] have over 70% homology to the nucleotide sequence shown under SEQ ID NO:1, and
  - d) nucleic acid molecules whose nucleotide sequence deviates from the sequence of the nucleic acid molecules stated under a) or b)[a), b) or c)] owing to the degeneracy of the genetic code.

31. (Amended) A nucleic acid molecule which specifically hybridizes[,] with a nucleic acid molecule as claimed in claim 26, under highly stringent conditions, wherein the hybridization temperature is 68°C and the wash temperature is 68°C.

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## Annex 1

Sequence alignment: Nucleotide Seq. from WO 00 08175 (alphaGlucPT) and WO 97 24448 (alphaGlucTaylor)

[Parameter justieren](#) | [FAQs zur MView](#) | [Index for MView](#) | [Groupmaps](#) | [Colormaps](#) | [My Alignments](#)

Alignment alphagluc.msf am 20.1.2003 → Output v. alphagluc kann markiert werden und mit Copy-Paste in Word 2000 (Nicks Compi) hinzugefügt werden.

| ClustalW 1.8 Parameters   | MView Parameters (output)                    |
|---|--|
| → fast pairwise alignment followed by multiple alignment  |  |
| ktuple=1<br>topdiag=5<br>window=5<br>pairgap=3<br>gapopen=10<br>gapextend=0.05<br>matrix: Gonnet<br>nopgap<br>nohgap<br>gapdist=8 (gaps < 8 residues from another gap are penalized more)<br>endgaps (means 'OFF': gapdist does not apply for gaps at ends of sequence) | maxdiv=40<br><br>consensus ignore: singleton |

Identities computed with respect to: (1) alphaGlucTaylor

Colored by: consensus/80% and group property

Consensus Symbols { Members in Class }

|             |      |   |
|-------------|------|---|
| alcohol     | => o | { S, T }                                  |
| aliphatic   | => l | { I, L, V }                               |
| aromatic    | => a | { F, H, W, Y }                            |
| charged     | => c | { D, E, K, R }                            |
| hydrophobic | => h | { A, C, F, G, I, K, L, M, P, T, V, W, Y } |
| negative    | => - | { D, E }                                  |
| polar       | => p | { C, D, E, H, K, N, Q, R, S, T }          |
| positive    | => + | { H, K, R }                               |
| small       | => s | { A, C, D, G, N, P, S, T, V }             |
| tiny        | => u | { A, G, S }                               |

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turnlike => t {A, C, D, E, G, H, K, N, Q, R, S, T}

|                 |        |   |
|-----------------|--------|---|
| alphaGlucTaylor | 100.0% | 1 [ MRAPLLYPLLLLLLFVTSAYSWKKEEFRNCQTPFCKRARSRKPTGSC : 50      |
| alphaGlucPT     | 20.9%  | -----   |
| alphaGlucTaylor | 100.0% | 51 NLRVADVSISDGDIAKLVKEENESEPNKLVTLSVYQDGVMRVKI : 100         |
| alphaGlucPT     | 20.9%  | -----PKRPRVHSQH-----ILHRPA-----                               |
| alphaGlucTaylor | 100.0% | 101 DEDQNLFTNPPKKRFEVPEVIEEDFLNTKLWLTRVKEEIQIDGVSSFSSVF : 150 |
| alphaGlucPT     | 20.9%  | -----   |
| alphaGlucTaylor | 100.0% | 151 YLSDGYEGVLRHDPEVFTARES[SGKR]SIN[LPDFEQLREKKEG : 200       |
| alphaGlucPT     | 20.9%  | -----HRGYSRYPAVSHGALLSMM-----                                 |
| alphaGlucTaylor | 100.0% | 201 DDWEEKFRSHTDTRPYGPQSI[VSFYFADFVGIPEHATSPALKPT : 250       |
| alphaGlucPT     | 20.9%  | -----IV-YDRISIK-----  |
| alphaGlucTaylor | 100.0% | 251 KGPNVEEYSEPYRLFNLDVFEYLHESPPGLYGSIPFMISFTHGKARGSSG : 300  |
| alphaGlucPT     | 20.9%  | -----V-----I-----   |
| alphaGlucTaylor | 100.0% | 301 FFWLNAAEMQIDVLGSGWNSDESSKIMLPSDKHRIDLWMSESVVTFB : 350     |
| alphaGlucPT     | 20.9%  | -----GILIYI-----  |
| alphaGlucTaylor | 100.0% | 351 STFIIGKD[R]SVT[SMPOLFATAYWNRDEEVYNDS : 400                |
| alphaGlucPT     | 20.9%  | -----A-----STEMEDQOLIAAMPYWSFGFAGKNIDELVD                     |
| alphaGlucTaylor | 100.0% | 401 KFDEHDYDFTLALERTKYMWRLLNPERM--QKIAAKG : 450               |
| alphaGlucPT     | 20.9%  | -----SYAKSRULE---MTDYMDPDLPLPANLERVIFFLRJHQND                 |
| alphaGlucTaylor | 100.0% | 451 RHM[KRDESHIPKEALFTEKYYVKDATGKD[DWC]SS : 500               |
| alphaGlucPT     | 20.9%  | -----QKYI[L]G[SINNTDTYRRGMEAD---VFIKRDNMPQVVNVY               |
| alphaGlucTaylor | 100.0% | 501 T[LL]EIKSWISDKFSLDSYVGSTKYIYWNDMPT-----EP[V : 550         |
| alphaGlucPT     | 20.9%  | -----PF[ATEVFRNEIEKFQDLVPFDGWLDMNELSFITSPPTPS-T               |
| alphaGlucTaylor | 100.0% | 551 NG[EV-----M[RDALIHGVHRELISVYFHMGSID : 600                 |
| alphaGlucPT     | 20.9%  | DD[PYKINNSGDHLPINYR[ATSTHDTMEYNV[LALESRAVYS                   |
| alphaGlucTaylor | 100.0% | 601 Q[LKRGDGKD[VI[AFA[QGA[WT[EHRV[V[MV : 650                  |
| alphaGlucPT     | 20.9%  | -----AV[NVTG-K[TRV[S-----G[TSH-----A[TNDAY[ITI                |
| alphaGlucTaylor | 100.0% | 651 [TLSIS[VESE[VG[FC[PDT[LVFTI[YV[Y[F[G[AHH : 700            |
| alphaGlucPT     | 20.9%  | -----SFGLF[PMV[IC[SS[TE[---C[TD[L[F[ASD[SAK                   |
| alphaGlucTaylor | 100.0% | 701 KRR[PWLFGERNTQLMREAIHV[MY[WT[FR[NSFTS[V[BID : 750         |



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|                 |        |   |       |
|-----------------|--------|---|-------|
| alphaGlucPT     | 20.9%  | TPQ[REDACTED]LYSW-DSVAAA[KV]LGL[REDACTED]QI[REDACTED]M[REDACTED]MY[REDACTED]H--IK[REDACTED]I[REDACTED]  |       |
|                 |        |   | 8-800 |
| alphaGlucTaylor | 100.0% | WME[REDACTED]G[REDACTED]E[REDACTED]S[REDACTED]S[REDACTED]NDEA[REDACTED]MV[REDACTED]NLLVQGVYTEKPKH[REDACTED]SV[REDACTED]L[REDACTED]GEESWYDLR   |       |
| alphaGlucPT     | 20.9%  | FFS[REDACTED]S[REDACTED]Q[REDACTED]A[REDACTED]T[REDACTED]D[REDACTED]I[REDACTED]S[REDACTED]T[REDACTED]L[REDACTED]K[REDACTED]U[REDACTED]VMIS[REDACTED]PILKQGAT[REDACTED]SDA[REDACTED]F[REDACTED]AGNWFDLFN |       |
|                 |        |   | 801   |
| alphaGlucTaylor | 100.0% | FTSASAY[G]EHTHKYEVSE[S]PSFOP[A]T[I]PRKDRLRRSSTOMENDPY   |       |
| alphaGlucPT     | 20.9%  | YSRSVSL[REDACTED]Q[REDACTED]TYMTLDAPP[H]NVHVAE[N]LVMOGE-AMTTQAAQRTAF  |       |
|                 |        |   | 851   |
| alphaGlucTaylor | 100.0% | TIVIA[REDACTED]N[REDACTED]A[REDACTED]F[REDACTED]GELYI[REDACTED]GKSYEFKQ[REDACTED]A[REDACTED]F-IL[REDACTED]WEAY[REDACTED]FQMOPRLQ  |       |
| alphaGlucPT     | 20.9%  | K[REDACTED]LVV[REDACTED]S[REDACTED]NS[REDACTED]G[REDACTED]LFVDD[REDACTED]EVQMGREG[REDACTED]RWTLV[REDACTED]FNSN[REDACTED]IGNKIVVK  |       |
|                 |        |   | 901   |
| alphaGlucTaylor | 100.0% | LAVTH---FPSECTV[REDACTED]RII[REDACTED]LSPGFTAT[REDACTED]TALIEPGNKKV[REDACTED]IELGPLF  |       |
| alphaGlucPT     | 20.9%  | SE[REDACTED]VNNGRYALDQQLVL[REDACTED]KVT[REDACTED]FENVRG[REDACTED]SYELVGSHQQGNTTMKESL  |       |
|                 |        |   | 951   |
| alphaGlucTaylor | 100.0% | I[REDACTED]GNRGSVPT[REDACTED]RKPNVR[REDACTED]TDDWSIQIL---   |       |
| alphaGlucPT     | 20.9%  | K[REDACTED]SGQFVTME[REDACTED]SGMSIL[REDACTED]GKEFKLELYIIT   |       |
|                 |        |   | 980   |

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